

K811449 HAEMONETICS 1000ML COMPONENT BAGJul 1, 1981
40 days to decisionK811449 · Product code: **KSR** · Hematology
Source: <https://www.510kdatabase.net/k811449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, Empty, For Collection & Processing Of Blood & Blood Components (KSR)
Date received	May 22, 1981
Decision date	Jul 1, 1981
Days to decision	40 days
Third-party review	No

APPLICANT

Company	Haemonetics Corp.
Location	Mchenry, IL, US
Website	http://www.haemonetics.com/
510(k) history	28 submissions · 28 cleared · 1980-2012

Haemonetics Corp. is a global provider of blood and plasma supplies and services. Founded in the 1970s, the company expanded to offices in 16 countries and serves markets across Asia, Europe, and the Americas. The company has received FDA 510(k) clearances from total submissions between 1980 and 2012. Anesthesiology devices represent the dominant category, including autotransfusion systems and blood recovery technologies. This regulatory record reflects the company's historical focus on perioperative blood management solutions. Notable cleared devices include the ORTHOPAT...